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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/964,338	09/28/2001	Sybille Marie Hunt	Q-66431	3699

7590

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EXAMINER

KAPUST, RACHEL B

ART UNIT

PAPER NUMBER

1647

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/964,338

Applicant(s)

HUNT ET AL.

Examiner

Rachel B. Kapust

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-16 and 22-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-16 and 22-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 September 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/000,442.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4</u> | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Priority

It is noted that this application claims subject matter disclosed in prior Application No. 09/000,442, and the specification has been amended to show that the application has been allowed. However, the specification needs to be amended to include the current status of the parent application, which is that it has issued as U.S. Patent No. 6,340,574.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on May 3, 2002 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

Drawings

Figures 3 and 8A are objected to under 37 CFR 1.83(a) because they are not of sufficient quality to provide an understanding of the disclosed invention. Figure 3 is supposed to be a Western blot and figure 8A is supposed to be a Northern illustrating IGF-1 mRNA expression. However, the figures are uninterpretable. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

The following is a quotation of 37 CFR § 1.821 (d) which sets forth rules regarding applications containing sequence listings:

Where the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO:" in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application.

On page 4 of the specification, line 14, Applicants refer to the "TATAA" sequence. The sequence is listed in the sequence listing as SEQ ID NO: 4. The specification needs to be amended so that the sequence is preceded by its sequence identifier.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(e), (f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 7-16 and 22-30 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Mather *et al.*, U.S. Patent 6,235,498, in view of Efrat *et al.* (1995), *Proc. Natl. Acad. Sci. USA* 92: 3576-3580 and Kushner *et al.*, U.S. Patent 5,089,397.

Mather *et al.* teach a method for creating host cells to produce proteins necessary for their own survival. This method comprises "transforming the host cell with a nucleic acid encoding the particular polypeptide factor...and culturing the transformed host cells in a medium lacking the particular polypeptide factor" (column 3, lines 30-38). Mather *et al.* further teach that the polypeptide factor may be a hormone, growth factor, peptide hormone, autocrine factor, transport protein, oncogene/proto-oncogene (column 4, lines 31-35). More specifically, Mather *et al.* teach that cells in serum-free medium generally require insulin and transferrin in a serum-free medium for optimal growth, thus these factors would be appropriate to use in the method (column 7, lines 1-3). Insulin, proinsulin, insulin-like growth factor I and II can all be used (column 4, lines 37-47). Regarding suitable host cells, Mather *et al.* teach that host cells are "those vertebrate cells capable of growth in culture and expressing a desired protein and a polypeptide factor(s). Suitable host cells include...Chinese hamster ovary cells-DHFR" (column

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5, lines 36-43). Mather *et al.* further teach that the amounts of the required polypeptide factors needed will vary and that some factors may be needed only when cells are initially plated, or may be needed at higher concentrations when the cells are at low density (column 6, lines 50-55). In addition, Mather *et al.* teach the need to control the levels of protein present in column 7, lines 20-35 and teach that optimal levels may be either higher or lower than physiological levels. However, Mather *et al.* do not teach means of regulating the levels of the polypeptide factors. Means of regulating expression of proteins are taught by Efrat *et al.* and Kushner *et al.*

Efrat *et al.* teach regulation by *tetR* and additionally by *lacZ*, as specified in instant claims 8 and 23. Moreover, Efrat *et al.* teach that the *tetR* system can be used for regulating cell proliferation by regulating the expression of the *TAg* oncoprotein in transformed β cells.

Kushner *et al.*, U.S. patent 5,089,397, teach the use of various members of the metallothionein promoter family for controlled protein expression in mammalian systems (columns 1 and 2), as specified in instant claims 9, 10, 24, and 25.

It would have been obvious for one of skill in the art at the time of the invention, and one would have been motivated to do so, to modify the teachings of Mather *et al.* with Efrat *et al.* or Kushner *et al.* to produce cells transfected with DNA encoding proteins required for survival under the control of a repressor system. One of ordinary skill would have been motivated to do so because Mather *et al.* teach cells that can produce their own required factors, and further teach that the required levels of these factors vary with the status of the cells, and Efrat *et al.* and Kushner *et al.* teach means by which the level of the factors produced by the cells can be varied. Thus, one of ordinary skill in the art would expect that the repressor systems of Efrat *et al.* and Kushner *et al.* would be useful modification to the system taught by Mather *et al.*

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NO CLAIMS ARE ALLOWED.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel B. Kapust whose telephone number is (703) 305-0634.

The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

RBK
8/22/03


JANET ANDRES
PATENT EXAMINER